#11

verified the applicant's claim that the new drug application (NDA) for VALTREX® (NDA 20–487) was initially submitted on June 23, 1994.

3. *The date the human drug was approved:* June 23, 1995. FDA has verified the applicant's claim that NDA 20–487 was approved on June 23, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,052 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 5, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 5, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–29809 Filed 12–6–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0302]

Determination of Regulatory Review Period for Purposes of Patent Extension; ULTANE™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ULTANE™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brain J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ULTANE™ (sevoflurane). ULTANE™ is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ULTANE™ (U.S. Patent No. 4,250,334) from Baxter International, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 25, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ULTANE™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ULTANE™ is 3,418 days. Of this time, 3,086 days occurred during the testing phase of the regulatory review period, while 332 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* January 29, 1986. The applicant claims January 10, 1986, as the date the investigational new drug (IND) became effective. However, FDA records indicate that the correct IND effective date was January 29, 1985, which was 30 days after FDA receipt of IND 27,645 on December 30, 1985.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* July 11, 1994. The applicant claims July 8, 1994, as the date the new drug application (NDA) for ULTANE™ (NDA 20–478) was initially submitted. However, FDA records indicate that the applicant submitted NDA 20–478 on July 8, 1994, and the agency received the NDA on July 11, 1994, which is considered to be the NDA initially submitted date.

3. *The date the application was approved:* June 7, 1995. FDA has verified the applicant's claim that NDA 20–478 was approved on June 7, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 5, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore,

any interested person may petition FDA, on or before June 5, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–29808 Filed 12–6–95; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Forms Undergoing Paperwork Reduction Act Review

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Health Education Assistance Loan (HEAL) Program Physician's Certification of Borrower's Total and Permanent Disability Form—New—This form, completed by the HEAL borrower, the borrower's physician, and the holder of the loan, is used to certify that the HEAL borrower meets the total and permanent disability provisions. The PHS will use this form to obtain precise information about the disability claim which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, (2) pertinent information supplied by the certifying physician, (3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death, and (4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in a disability claim not being honored.

Type of respondent	Number of respondents	Responses per respondent	Average burden per response	Total burden (hours)
Borrower	42	1.0	0.08	3
Physician	42	1.0	2.75	116
Lender	35	1.2	0.17	7

Estimated Total Annual Burden: 126 hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 1, 1995.

J. Henry Montes,

Associate Administrator for Policy Coordination

[FR Doc. 95–29810 Filed 12–6–95; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 36 U.S.C. 207 or pursuant to 42 U.S.C. 241 to achieve expeditious commercialization of results of federally-funded research and development.

ADDRESSES: Licensing information for the technologies referenced below may be obtained by contacting Stephen Finley, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056 ext 215; fax 301/402–0220).

cDNA Sequence of a Clone Encoding Arylalkylamine N-acetyltransferase

Klein et al. (NICHD)

[DHHS Reference No. E–161–95/0]

and

Human Gene Encoding Serotonin N-acetyltransferase

Klein et al. (NICHD)

[DHHS Reference No. E–222–95/0]

The identification of an arylalkylamine N-acetyltransferase (AA–NAT) mRNA in the brain and the cloning of ovine and human cDNAs encoding for the pineal enzyme serotonin N-acetyltransferase. These findings open a new area of research—the importance of AA–NAT in the regulation of brain serotonin and the development of drugs which raise serotonin levels by inhibiting this enzyme. This enzyme is the rate-controlling step in the conversion of serotonin to melatonin. The hormone melatonin has been linked to controlling circadian rhythms. Development of regulators of the synthesis of the hormone melatonin may be the preferred route to controlling seasonal reproduction cycles or sleep cycles of vertebrates. Activators of the serotonin N-acetyltransferase may be beneficial to induce or enhance the quality of sleep at night. Inhibitors of serotonin N-acetyltransferase may lead to drugs that stimulate the levels of alertness and physical activity or delay the onset of fatigue. Licenses for the cDNAs encoding for this enzyme or the production of the enzyme are available.

Patent Information

PATENT EXTENSION REQUESTS

Patent extension requests calculated by sponsor based on drug development and FDA review times.

Drug	Number	Patentee(s)	Assignee	Issue Date	Expiration Date	Extension Request Date
Adenoscan (adenosine)	5,070,877	Syed Mohiuddin and Daniel Hilleman	Medco Research	12/10/91	12/10/2008	5/18/2009
Cellcept (mycophenolate mofetil)	4,753,935	Peter Nelson, *et al.*	Syntex	6/28/88	6/28/2005	5/3/2009
Prevacid (lansoprazole)	4,628,098	Akira Nohara, *et al.*	Takeda-Abbott	12/9/86	12/9/2003	8/10/2008
Ultane (sevoflurane)	4,250,334	Clifford Coon and Robert Simon	Baxter International (sublicensed to Maruishi Pharmaceutical and Abbott Labs)	2/10/81	12/26/99 [GATT-extended from 2/10/98]	12/26/2004
Zinecard (dexrazoxane)	4,275,063	Andrew Creighton	British Technology Group Limited (sublicensed to Pharmacia)	6/23/81	6/23/98	6/23/2003

PATENT ACTIVITY

Hoffmann-La Roche
IL-2

PTO declares an interference on patent claims for homogeneous human interleukin-2 by Hoffmann-La Roche and Memorial Sloan-Kettering Cancer Center, the company announces. Memorial Sloan-Kettering already has been issued a patent for IL-2, while Roche's patent is pending. The PTO uses an interference to determine the first inventor for claims.

ILEX Oncology
DFMO cancer treatment

San Antonio, Texas-based company aquires all patent rights pertaining to the use of diflouromethylornithine (DFMO) in the treatment of cancer and other infections from Hoechst Marion Roussel. Hoechst Marion Roussel will transfer its IND, manufacturing technology, regulatory documents and entire supply of formulated DFMO to ILEX, which will initiate its clinical trials of the drug in 1996. ILEX plans to enter into a clinical trial agreement with the National Cancer Institute. NCI is currently sponsoring *Phase III* trials of DFMO in patients with recurrent primary brain tumors. ILEX, founded in 1994, states that its mission is to accelerate the development and commercialization of anticancer drugs, in part by manufacturing oncology products for other companies.

Immune Response
HIV virus vaccine

A patent covering its core HIV therapy technology for a "Salk" killed-virus vaccine has been awarded, Immune Response announces. The Carlsbad, California-based company already has been issued a U.S. patent for this technology. *Phase III* trials are planned for Immune Response's HIV virus vaccine.

representing an interest in, loans or receivables of a type generally made to or due from consumers) (hereinafter "CRRs");

(4) Commercial paper.

Applicants have also applied for approval under § 225.25(b)(16) of Regulation Y (12 CFR 225.25(b)(16)) to engage, *de novo*, through Company in underwriting and dealing in securities and money market instruments that state member banks are expressly authorized to underwrite and deal in under section 16 of the Glass-Steagall Act (12 U.S.C. 24 Seventh), including U.S. government obligations and general obligations of states and their political subdivisions. The foregoing activities are presently conducted by Applicants' principal banking subsidiary, Marine Midland Bank, N.A., and would be transferred to Company in connection with this proposal.

Upon approval of the proposal, Company would commence underwriting and dealing in ineligible securities through Company's offices in New York, New York, serving customers throughout the United States. Company may establish offices in other locations.

Section 4(c)(8) of the Bank Holding Company Act provides that a bank holding company may, with Board approval, engage in any activity "which the Board after due notice and opportunity for hearing has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto." Applicants have applied to engage in the same activities with the same limitations as proposed in the applications of J.P. Morgan & Company Incorporated and Bankers Trust New York Corporation, previously approved conditionally by the Board on April 30, 1987. Citicorp, J.P. Morgan & Co. Incorporated, and Bankers Trust New York Corporation (Order dated April 30, 1987). In its Order, the Board authorized Citicorp, J.P. Morgan & Co. Incorporated, and Bankers Trust New York Corporation to engage through subsidiaries in underwriting commercial paper, 1–4 family mortgage-backed securities and municipal revenue bonds within a prudential framework of conditions and subject to 5 percent gross revenue and market limitations.

The application presents issues under section 20 of the Glass-Steagall Act (12 U.S.C. 377). Section 20 of the Glass-Steagall Act prohibits the affiliation of a member bank, such as Marine Midland Bank, N.A., with a firm that is "engaged principally" in the "underwriting, public sale or distribution" of securities. Applicants state that Company would not be "engaged principally" in such activities on the basis of restrictions that would limit the amount of the proposed activity relative to the total business conducted by Company and relative to the total market in such activity.

Any request for a hearing on these questions must comply with § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)).

The application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of New York.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551, not later than June 1, 1987.

Board of Governors of the Federal Reserve System, May 6, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87-10714 Filed 5-11-87; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Federal Advisory Committee, Interagency Committee on Smoking and Health; Availability of 1986 Annual Report

ACTION: Notice of availability.

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463 (5 U.S.C. Appendix 2), the Fiscal Year 1986 annual report for the following Federal advisory committee utilized by the Centers for Disease Control has been filed with the Library of Congress:

Interagency Committee on Smoking and Health

Copies are available to the public for inspection at the Library of Congress, Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue SE., Washington, DC (telephone 202/287-6310). Additionally, on weekdays between 9 a.m. and 4:30 p.m. copies will be available for inspection at the Department of Health and Human Services, Department Library, HHS North Building, Room 1436, 300 Independence Avenue SW., Washington, DC (telephone 202/245-6791).

Dated: May 6, 1987.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 87-10703 Filed 5-11-87; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[FDA 225-86-8251]

Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Patent and Trademark Office (PTO) and FDA. The MOU establishes procedures whereby FDA assists PTO in determining a product's eligibility for patent term restoration and procedures for exchanging information between FDA and PTO regarding regulatory review period determinations, due diligence petitions, and informal FDA hearings.

DATE: The memorandum of understanding became effective September 17, 1986.

FOR FURTHER INFORMATION CONTACT: Walter J. Kustka, Intergovernmental and Industry Affairs Staff (HFC-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1583.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all agreements and memorandum of understanding between FDA and others shall be published in the Federal Register, the agency is publishing this memorandum of understanding.

Dated: May 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration

I. Purpose

This agreement establishes the procedures whereby the Food and Drug Administration (FDA) assists the Patent and Trademark Office (PTO) in determining a product's eligibility for patent term restoration under 35 U.S.C. 156. It also establishes procedures for exchanging information between FDA and PTO regarding regulatory review period

Additionally, FDA will publish its findings in the **Federal Register.**

D. Supplemental Information:

Should either agency receive information which is relevant to the patent term restoration of a patent during any stage of these eligibility or regulatory review period determinations, that agency will promptly notify the other and provide documentation as available.

E. Availability of Information:

Copies of all letters required by this agreement and exchanged between PTO and FDA will be placed in the file for each product subject to patent term restoration. These files are available for review at FDA's Dockets Management Branch (HFA-305), Room 4-62 5600 Fishers Lane, Rockville, Maryland 20857 and at the Patent and Trademark Office, Crystal Plaza Building 2-9A08, 2011 Jefferson Davis Highway, Arlington, Virginia 22202.

IV Names and Addresses of Participating Parties

A. Patent and Trademark Office, Washington, DC 20231.

B. Food and Drug Administration, 5600 Fishers Lane, Rockville Maryland 20857.

V. Liaison Officers

A. *Liaison Officer for the Patent and Trademark Office:* Director, Patent Examining Group 120, (currently Charles E. Van Horn, Esq.), Patent and Trademark Office, Washington, DC 20231, (703-557-3637).

B. *Liaison Officer for the Food and Drug Administration:* Director, Health Assessment Policy Staff (HFY-20), (currently Ronald L. Wilson), Office of Health Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, (301-443-1382).

VI. Period of Agreement

This agreement, when accepted by both parties, will be effective indefinitely. It may be modified by mutual written consent or terminated by either party upon a thirty day advance written notice to the other party.

APPROVED AND ACCEPTED FOR THE PATENT AND TRADEMARK OFFICE.

By: Donald J. Quigg,

Title: Assistant Secretary and Commissioner of Patents and Trademarks.

Dated: September 17, 1986.

APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION.

By: John M. Taylor.

Title: Acting Associate Commissioner for Regulatory Affairs.

Dated: September 3, 1986.

[FR Doc. 87-10713 Filed 5-11-87; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F. of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA) **Federal Register** Vol. 51, No. 191, pp. 35288-35291, dated Thursday, October 2, 1986) is amended to reflect a reorganization within the Office of the Associate Administrator for Management and Support Services (OAAMSS). The reorganization of the Office of Health Program Systems in the Bureau of Data Management and Strategy will consolidate and centralize responsibility for the Group Health Plan System into one division, the Division of Capitation Systems, as well as provide a focus for development of systems in support of the private health plan option initiatives.

The specific changes to Part F. are as follows:

- Section FH.20.F.5., Office of Health Program Systems is deleted in its entirety and replaced by an updated functional statement to read as follows:

5. Office of Health Program Systems (FHE8)

Designs, develops, implements and maintains Automated Data Processing (ADP) and telecommunications systems and software, data files and formats, and manual procedures required to support the Agency's programmatic mission from operational, program management, and quality control aspects. Establishes and maintains a national file of eligible Medicare beneficiaries. Establishes and maintains a history of Medicare benefit utilization. Integrates entitlement data and information from other programs (e.g., Medicaid, Veterans Administration) into Medicare files. Receives and responds to queries regarding beneficiary entitlement and benefit and deductible status from a nationwide network of Medicare fiscal agents. Provides program data and related information to authorized requestors. Maintains systems that support certification of providers of service in the Medicare and Medicaid programs. Determines and reconciles payment liability for group health organizations. Maintains systems that support certification of health maintenance organizations and capitation demonstration projects. Prepares billings for and receives and processes ADP records for Medicare premium remittances from third party payors and beneficiaries. Prepares a variety of program management reports (e.g., workloads, processing times) for distribution throughout the Agency, Department, and Medicare fiscal agents. Provides ADP support to the Agency for quality control systems and beneficiary and provider overpayment systems. Consults with central and regional office components and other government agencies to define programmatic ADP system performance requirements. Negotiates, reviews, and approves systems designs. Consults with Bureau of Data Management and Strategy components to define ADP and teleprocessing resource requirements and provides input to the budget planning and procurement processes.

Insures awareness of and compliance with government-wide and local security and privacy requirements within the Office. Directs and coordinates implementation of PRISM Redesign Process for Office. Serves as Data Base Administrator for the Office. Provides technical support to Office programmers. Provides office focus for Systems Security, Standards and Documentation.

A. PRISM/Redesign Staff (FHE8-1)

Plans, organizes, coordinates, and controls the activities required to assure the timely, accurate, cost-effective, and successful completion of the Health Insurance/Supplementary Medical Insurance (HI/SMI) and Program Management (PM) Logical Application Groups (LAG) development, conversion and implementation under the Project to Redesign Information Systems Management (PRISM). Advises the Director, Office of Health Program Systems, and executives of various HCFA components in the preparation of short, intermediate and long-range plans for the improvement of the HCFA information systems. Keeps informed of organizational, legislative, administrative and technological changes that affect the PRISM LAG processes and impact upon future planning. Works continuously with the appropriate levels of management and with members of the staff in the Bureaus and Offices to provide liaison and assistance with respect to Agency-wide planning and participates in planning activities to ensure that the Agency's ADP systems meet the needs of the user community for high quality, reliable data. Develops and designs methods and processes which assure the quality of the enhancements to existing systems and the development of new systems for PRISM LAGs. Plans and conducts comprehensive analysis of complex and diversified areas such as system analysis and design methodologies, computer programming methodologies, techniques, software testing, validation and systems acceptance, configuration of HCFA ADP/TC resources, and data base security and integrity. Develops ADP systems quality assurance and software testing standards and

determinations, due diligence petitions and informal FDA hearings under the law.

II. Background

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1987 (Pub. L. 98-417) was designed to create new incentives for research and development of certain products which are subject to premarket government approval. These provisions enable the owners of patents on certain human drugs, medical devices, and food or color additives to attempt to restore to the terms of those patents some of the patent time lost while awaiting premarket government approval.

Under the patent term restoration sections of the Act, a patent which claims a human drug product, medical device, food or color additive first approved for marketing after September 24, 1984 may qualify for patent term extension. Regardless of whether the patent claims a product, a method of using a product, or a method of manufacturing a product, the applicant for a patent term extension must establish that:

(1) The patent has not expired (35 U.S.C. 156(a)(1)).

(2) The patent has never been extended (35 U.S.C. 156(a)(2)).

(3) The application for extension is submitted by the owner of record of the patent or its agent and includes details relating to the patent and regulatory review time spent in securing FDA approval (35 U.S.C. 156(a)(3)).

(4) The product has been subject to a regulatory review period within the meaning of 35 U.S.C. 156(g) before its commercial marketing or use (35 U.S.C. 156(a)(4)).

(5) The approval:

(A) Is the first permitted commercial marketing or use of the product, or

(B) In the case of products manufactured using recombinant DNA technology, it is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent (35 U.S.C. 156(a)(5)), and

(6) The application for extension of the term of the patent was submitted to PTO within 60 days of FDA approval of the commercial marketing application (35 U.S.C. 156(d)(1)).

While it is the responsibility of the Commissioner of Patents and Trademarks to decide whether an applicant has satisfied these six conditions, FDA possesses expertise and records regarding the last four and has certain direct responsibilities under 35 U.S.C. 156 for determining the length of the regulatory review period. Consequently, to facilitate eligibility decisions and permit FDA and PTO to carry out their responsibilities under 35 U.S.C. 156, the FDA and PTO have entered into this agreement. This agreement is consistent with the authority contained in section 702(d) of the Federal Food, Drug, and Cosmetic Act.

Under this agreement, FDA, upon receipt of a written request from PTO, will convey to PTO the following information regarding eligibility for extension: (1) Whether a product has undergone a regulatory review period within the meaning of 35 U.S.C. 156(g) prior to commercialization, (2) whether the marketing permission was for the first permitted commercial marketing or use of that product, or, in the case of recombinant marketing or use of that product, or, in the case of recombinant DNA technology, whether such commercial marketing or use was the first permitted under the process claimed in the patent, and (3) whether the patent term extension application, as well as any other relevant information. Similarly, upon a request by PTO and the receipt of a copy of the application for patent term extension, FDA will determine the ~~application for patent term extension, FDA will determine the~~ length of the regulatory review period for the approved product.

The procedures covered by this agreement extend from the date of PTO's request for information on eligibility to the resolution of due diligence petitions and information hearings. The regulatory review period determination is not final until due diligence petitions and informal hearings, if any, have been resolved. A certificate for extension of the term of a patent may not issue from PTO until the regulatory review period determination is final unless an interim extension appears warranted under 35 U.S.C. 156(e)(2).

III. Substance of the Agreement: Patent Term Extension Applications Under 35 U.S.C. 156

A. Eligibility Determination Assistance:

1. Upon deciding that a patent term extension application is complete and meets basic formal requirements, the PTO will send a written request to FDA requesting that FDA:

a. verify whether the product:

(1) Was subject to a regulatory review period within the meaning of 35 U.S.C. 156(g) prior to its commercial marketing or use, and

(2) Represents either the first permitted commercial marketing or use of that product, or, in the case of recombinant DNA technology, the first permitted commercial marketing or use of the product manufactured under the process claimed in the patent.

b. Inform PTO whether the patent term restoration application was submitted within 60 days after the product was approved.

2. Additionally, PTO, in its written request, shall clearly state that it is not requesting determination of the product's regulatory review period at this time.

3. FDA will consult its records and experts and, through the Director of the Health Assessment Policy Staff, Office of Health Affairs, issue a written response to the Director of Patent Examining Group 120, PTO, on each of these questions.

4. FDA, consistent with the authority contained in section 702(d) of the Federal Food, Drug, and Cosmetic Act with respect to drugs, will provide PTO with any other information relevant to the product's eligibility.

5. FDA, upon written request, will also provide assistance to PTO in petitions before the Commissioner of Patents and Trademarks regarding eligibility determinations.

B. Regulatory Review Period Determinations:

1. Should the PTO decide that the product is eligible for patent term restoration, it will send FDA a copy of the application for patent term restoration and a written request to determine the length of the product's regulatory review period. The copy and request will be sent to FDA within 60 days of the application's receipt by PTO.

2. FDA will consult its records, determine the entire length of the regulatory review period, and, through the Associate Commissioner for Health Affairs, issue a written statement of that determination to the Commissioner of Patents and Trademarks. The determination will be made within 30 days after the receipt of the application and written request from PTO. Additionally, FDA will publish its determination in the **Federal Register.**

C. Due Diligence Petitions and Hearing Requests:

1. Due diligence petitions must be filed at FDA within 180 days of the publication of a product's regulatory review period in the **Federal Register.**

a. If no due diligence petition is received by FDA within the 180-day filing period, FDA will promptly notify PTO in writing that the regulatory review period determination is final.

b. If a due diligence petition which satisfies statutory and regulatory requirements is received by FDA,

(1) FDA will promptly notify PTO in writing of the receipt of the petition,

(2) PTO will refrain from issuing a certificate of extension pending a final determination of the regulatory review period unless an interim extension appears warranted under 35 U.S.C. 156(e)(2),

(3) FDA will determine whether the applicant acted with due diligence within 90 days after receipt of such a petition and will send written notification to the Commissioner of Patents and Trademarks as to any modification in the length of the regulatory review period, and

(4) FDA will also publish its due diligence determination, together with the full factual and legal bases for FDA's decision, in the **Federal Register.**

2. Requests for an informal hearing on FDA's due diligence determination must be received by FDA within 60 days of the publication of the due diligence determination in the **Federal Register.**

a. If FDA does not receive any request for an informal hearing within the 60 filing period, FDA will notify PTO in writing that the regulatory review period determination, as modified, if at all, by the due diligence determination, is final.

b. If FDA receives a request for an informal hearing within the 60 day filing period,

(1) FDA will notify PTO in writing of the hearing request,

(2) PTO will refrain from issuing a certificate of extension pending final determination of the regulatory review period unless an interim extension appears warranted under 35 U.S.C. 156(e)(2), and

(3) FDA will affirm or revise the determination that was the subject of the hearing within 30 days after completion of the hearing and will notify the Commissioner of Patents and Trademarks in writing of its decision and whether the determination of the regulatory review period is now final.

Claims. Infringement. Extension.

an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.".

Ante, p. 1585.

SEC. 104. Section 506 of such Act is amended by adding at the end the following:

Public availability.

"(i) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

"(1) if no work is being or will be undertaken to have the application approved,

"(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

"(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

"(4) if the Secretary has determined that such drug is not a new drug,

"(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

"(m) For purposes of this section, the term 'patent' means a patent issued by the Patent and Trademark Office of the Department of Commerce.".

Regulations. 21 USC 355 note.

SEC. 105. (a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.

(b) During the period beginning sixty days after the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.

Ante, pp. 1582-1584.

Ante, p. 1584.

Ante, p. 1586.

SEC. 106. Section 2201 of title 28, United States Code, is amended by inserting "(a)" before "In a case" and by adding at the end the following:

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.".

TITLE II—PATENT EXTENSION

SEC. 201. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 156A:

35 USC 156.

"§ 156. Extension of patent term

Claims.

"(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

"(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

"(2) the term of the patent has never been extended;

"(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

"(4) the product has been subject to a regulatory review period before its commercial marketing or use;

"(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

Marketing.

"(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

WEST'S FEDERAL PRACTICE MANUAL

Patent term extension and restoration, see § 3921.5.

LAW REVIEW COMMENTARIES

Patent reexamination reexamined. William G. Conger, Detroit Coll.L.Rev. 523 (1986).

LIBRARY REFERENCES

Patents ⇐133.
C.J.S. Patents § 167.

§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

(2) the term of the patent has never been extended;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which—

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product".

(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the product—

(A) before the expiration of the term of the patent—

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;